

5-26-81

PC-100  
TR-1186

DATE: May 15, 1981

SUBJECT: Goal 2E  
EPA Registration No.: 707-145

18AAA

FROM: Sherell A. Sterling  
FHB/TSS

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TO: Richard Mountfort  
Product Manager (23)

001186

Registrant: Rohm and Haas Company  
Independence Mall West  
Philadelphia, PA 19105

Active Ingredient:  
Oxyfluorfen.....22.6%  
Inert Ingredients.....77.4%

Background:

The applicant submitted Acute Range Finding Oral, Dermal, Eye and Skin Irritation studies for a new formulation of Goal 2E. A definitive Eye Irritation study was also submitted. These studies were conducted by the Rohm and Haas Toxicology Department in Spring House, Pennsylvania. The purpose of this submission is to demonstrate that the formulation change [redacted] would not result in a change of precautionary statements. The method of support is "cite-all."

Recommendations:

1. The Range-Finding Acute Oral, Acute Dermal, Eye and Skin Irritation studies are considered supplementary data. As such, they are not sufficient as sole support for the conditional registration of a product. In these studies an insufficient number of animals were tested. Only males were tested; equal numbers of males and females must be tested in the Acute Oral and Acute Dermal studies. However, FHB/TSS points out that the laboratory/registrant was aware that these studies were lacking since the report included a notice that these studies should not be considered definitive.

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MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

2. The Definitive Eye Irritation study is considered adequate and acceptable for conditional registration purposes.
3. The Acute Oral, Acute Dermal and Skin Irritation studies are considered Core Supplementary. However, when reviewed along with acute data on the currently accepted formulation, these data are sufficient to show that the formulation change does not require a change in the "Hazards to Humans and Domestic Animals" statements. Any revisions requested in this section are due to Agency revisions of standard statements, not a change in toxicity category.
4. An Acute Inhalation study was not submitted. Since the other acute toxicity parameters for this product are similar to those for the original product, an Acute Inhalation study is not necessary at this time.
5. The only changes in precautionary statements are minor changes under the "Physical or Chemical Hazards" section.

Labeling Recommendations:

1. The "Hazards to Humans and Domestic Animals" section must be revised as follows:

WARNING. Causes substantial but temporary eye injury and skin irritation. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield. This material may be harmful if swallowed.

Statement of Practical Treatment:

If in eyes: Flush with plenty of water. Get medical attention.

If on skin: Wash with plenty of soap and water. Get medical attention.

If swallowed: Do not induce vomiting. Call a physician. Do not induce vomiting or give anything by mouth to an unconscious person.

2. Under the "Environmental Hazards" section, the statement "Keep out of lakes, ponds or streams" must be revised to "Do not apply directly to water."
3. The "Physical or Chemical Hazards" section may maintain the statements:

Combustible. Keep away from heat and open flame.

Based on the flash point of this new formulation, these statements are not required.

4. The statement "Keep from freezing: store above 32°F" should be placed under the "Storage" heading in the "Storage and Disposal" section.

5. Please refer to the enclosed "Storage and Disposal" information sheets for currently accepted format and preferred wording for the "Storage and Disposal" section of the labeling.
6. All product bulletin statements must be revised to conform with revised labeling statements.

Review:

1. Acute - Range Finding Oral LD50; Rohm & Haas #80R-0225; March 24, 1981; Acc. No. 244786.

Procedure:

Groups of 3 male Sprague-Dawley rats received a dosage of "Goal 2E" at 0.5 g/kg or 5 g/kg. The test substance was administered as a 20% dispersion of the test substance in distilled water by oral gavage. Animals were observed for 14 days. All animals were subjected to necropsies.

Results:

At 5.0 g/kg, 3/3 rats died; no deaths at 0.50 g/kg. Observations included: hypothermia, moribund, ataxia, stained muzzle, lacrimation, ptosis, decreased righting reflex. Necropsy revealed: lungs reddened; gastric mucosa separated from serosa; red foci on gastric mucosa; severe autolysis. LD50 estimated at greater than 500 mg/kg.

Study Classification:

Core Supplementary Data. Not enough animals/dosage level. Only M tested.

2. Acute - Range Finding Dermal LD50;

Rohm & Haas #80R-0225; March 24, 1981; Acc. No. 244786

Procedure:

Groups of 2 male New Zealand white rabbits received an application of "Goal 2E" on the skin at 5.0 g/kg or 0.5 g/kg. Exposure was for 24 hours under occlusive wrap. Animals were observed for 14 days post-treatment. All rabbits were subjected to necropsies.

Results:

No mortalities. Observations included: weight loss; brown-stained anogenital area; diarrhea; scant droppings; vocalization upon dosing; severe erythema, slight edema; eschar; blanching; desquamation. Necropsy revealed: kidneys -- pale with pitted surface in 1/2 at 0.5 g/kg. The estimated LD50 was greater than 5 g/kg; however, substance was not totally absorbed.

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Study Classification:

Core Supplementary Data. Not enough animals tested. Only M tested.

3. Acute - Range Finding Eye Irritation; Rohm and Haas # 80R-0225; March 24, 1981; Acc. No. 244786.

Procedure:

Two New Zealand white rabbits each received 0.1 ml of "Goal 2E" in one eye. Eyes were not rinsed posttreatment. Eyes were evaluated at 4, 24, 48, 72 hours; 4 and 7 days.

Results:

At 24 hours, corneal opacity in 2/2 = 20; iris irritation in 2/2 = 5; conjunctival irritation in 1/2 = 14, 1/2 = 16. No irritation observed on day 7.

Study Classification:

Core Supplementary Data. Not enough animals tested.

4. Acute Definitive Eye Irritation:

Rohm & Haas #80R-0195; January 29, 1981; Acc. No. 244786

Procedure:

Nine New Zealand white rabbits each received 0.1 ml of "Goal 2E." Three of the eyes were flooded with water approximately 20-30 seconds post-dosing. Animals were observed for 21 days.

Results:

Three of the animals vocalized upon instillation of test substance into eyes. Unwashed eyes at 24 hours showed corneal opacity in 5/6=20, 1/6=40; iris irritation in 6/6=5; conjunctival irritation in 1/6=10, 2/6=16, 3/6=18. At 7 days corneal opacity observed in 1/6=5, 1/6=10, 1/6=15, 2/6=20, 1/6=40; blood vessels growing onto cornea of all 6 eyes; conjunctival irritation in 4/6=2, 1/6=4. By 21 days, only irritation was corneal opacity in 1/6=5 with blood vessels growing onto cornea in 6/6 eyes.

Washed eyes at 24 hours exhibited corneal opacity in 2/3=20, 1/3=40; iris irritation in 2/3=5; conjunctival irritation in 1/3=10, 2/3=16. By 7 days corneal opacity observed in 1/3=2, 2/3=5; conjunctival irritation in 1/3=2, 2/3=4. All irritation had subsided by day 21.

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Study Classification:

Core Guideline Data.

Toxicity Category:

II-WARNING. While unwashed eyes did show irritation at 21 days, it was minimal; reversibility was demonstrated.

5. Acute - Range Finding Skin Irritation; Rohm & Haas #80R-0225; March 24, 1981; Acc. No. 244786.

Procedure:

Two New Zealand white rabbits received 0.5 ml of "Goal 2E" at each of 2 sites, 1 abraded and 1 intact. Exposure was for 24 hours under occlusive wrap. Observations were recorded 24 hours and 72 hours post-application.

Results:

At 24 hours, erythema observed in 1/2=3, 1/2=4 at intact sites; at abraded sites, 1/2=3 and 1/2=4. Edema at both intact and abraded sites 2/2=3 at 24 hours. By 72 hours, erythema at both intact and abraded sites was 1/2=2 and 1/2=4; edema at both intact and abraded sites was reported as 1/2=2 and 1/2=3. Eschar noted at one abraded and one intact site at 24, 72 hours. Desquamation noted at 7 days. The "estimated" Primary Irritation Index is 6.

Study Classification:

Core Supplementary Data. Not enough animals tested. Should test at 4 sites (2 abraded, 2 intact) for each animal.

Enclosures

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Oxyfluorfen toxicology review

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The material not included contains the following type of information:

- ☐ Identity of product inert ingredients
  - ☐ Identity of product impurities
  - ☐ Description of the product manufacturing process
  - ☐ Description of product quality control procedures
  - ☐ Identity of the source of product ingredients//
  - ☐ Sales or other commercial/financial information
  - ☒ A draft product label
  - ☐ The product confidential statement of formula
  - ☐ Information about a pending registration action
  - ☐ FIFRA registration data
  - ☐ The document is a duplicate of page(s) \_\_\_\_\_
  - ☐ The document is not responsive to the request
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The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

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